

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL ADVISORY ALLERGY AND INFECTIOUS DISEASES COUNCIL

MINUTES OF MEETING

January 23-24, 1997

Building 31, Conference Room 10
National Institutes of Health
Bethesda, Maryland 20892

- I. REVIEW OF GRANT APPLICATIONS - (Closed to the Public)
- II. REMARKS OF THE DIRECTOR, NIAID - Anthony S. Fauci, M.D.
 - A. Consideration of Minutes of Previous Meeting
 - B. Dates of Future Council Meetings
 - C. Staff and Organizational Changes
 - D. Review of Operating Procedures for FY 1997
 - E. Budget Update
 - F. Legislative Update
 - G. Other Information Items
- III. ON-LINE REVIEW PILOT PROGRAM - John McGowan, Ph.D.
Acting Deputy Director, NIAID
- IV. DRG UPDATE: DISCUSSION OF REINVENTION AND REVIEW ISSUES
BY NEW DRG DIRECTOR - Ellie Ehrenfeld, Ph.D., Director,
Division of Research Grants, NIH
- V. EMERGING INFECTIOUS DISEASES: NIAID AND CDC ROLES

Stephanie James, Ph.D., Chief, Parasitology and International
Programs Branch, DMID, NIAID

Daniel Colley, Ph.D., Director, Division of Parasitic Diseases
National Center for Infectious Diseases, CDCP
- VI. REPORT OF THE DAIT COUNCIL SUBCOMMITTEE -
Robert Goldstein, M.D., Director, DAIT
- VII. REPORT OF THE JOINT MEETING OF AIDS SUBCOMMITTEE, NAAIDC, AND
AIDS RESEARCH ADVISORY COMMITTEE -
John Y. Killen, M.D. Director, DAIDS
- VIII. REPORT OF THE DMID COUNCIL SUBCOMMITTEE -
John La Montagne, Ph.D., Director, DMID
- IX. ADJOURNMENT
Roster of Members, NAAIDC*
Resume of Council Recommendations*

*Available from NIAID Committee Management Office
(301) 496-7601

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

NATIONAL ADVISORY ALLERGY AND INFECTIOUS DISEASES COUNCIL

MINUTES OF MEETING

January 23-24, 1997

The 125th meeting of the National Advisory Allergy and Infectious Diseases Council (NAAIDC) was convened at 8:30 a.m. on Thursday, January 23, 1997 in Conference Rooms 8, 9 and 10, Building 31, National Institutes of Health. Dr. Anthony S. Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), presided as Chairman.

In accordance with the provisions of Public Law 92-463, the meeting was open to the public from 1:00 p.m. to 4:00 p.m. on January 23, and from 8:00 a.m. to 4:45 p.m. on January 24. The meeting was closed to the public on January 23 from 8:30 a.m. to 1:00 p.m. and again from 3:30 p.m. to 4 p.m., for review and consideration of individual grant applications. Notice of the meeting was published in the *Federal Register*.

Council Members Present:

Dr. Janet Butel
Dr. Robert Couch
Mr. Martin Delaney
Dr. Jerrold Ellner
Dr. Laurie Glimcher
Ms. Louise Jacobbi
Dr. Howard Johnson
Dr. Warren Johnson, Jr.
Mr. Stephan Lawton
Mr. Garry Lyle
Dr. Paula Pitha-Rowe
Ms. Orvalene Prewitt
Ms. Emily Spitzer
Dr. W. Gary Tarpley
Dr. Judith Thomas
Ms. Mildred Williamson

Council Members Absent:

Dr. Samuel Silverstein
Dr. Lowell Young

Ex Officio Members Present:

Dr. Gary Carpenter, Walter Reed Army Medical Center
Dr. Daniel Colley, Centers for Disease Control and Prevention

Ex Officio Members Absent:

Dr. Fred Gordin, Veterans Administration
Dr. James Hughes, Centers for Disease Control and Prevention

AIDS Research Advisory Committee, NIAID Members Present:

Dr. Raphael Dolin
Dr. Gary Nabel
Dr. Marian Neutra
Dr. Charles Rinaldo
Dr. Cladd Stevens

Ex Officio & Liaison Members of ARAC Present:

Dr. Harold Jaffe

***Ad Hoc* Members Present:**

Dr. Abul Abbas
Dr. Jack Elias
Dr. Anne Gershon
Dr. Susan Pierce
Dr. Edmund Tramont
Dr. Richard Whitley

NIAID Staff Attending:

Ms. Lillian Abbey, Program Analyst, DMID
Ms. Kristin Adamson, Program Specialist, DAIT
Ms. Diane Adger-Johnson, Technical Information Specialist, PAB
Dr. Jeffrey Albert, Mathematical Statistician, BRB, DAIDS
Ms. Mary Allen, Clinical Trials Specialist, CDB, DAIDS
Mr. Bruce Anderson, Contract Specialist, CMB, DEA
Dr. Kathryn Aultman, Vector Biology Program Officer, PIPB, DMID
Dr. Phillip J. Baker, Lyme Disease Program Officer, BMB, DMID
Mr. Todd Ball, Chief, MGMS, GMB, DEA
Ms. Patricia Baron, Biologist, OSC, DAIDS
Ms. Mabel Battistone, Head, RSU, DEA
Dr. Fred Batzold, Chief, CSMB, TRP, DAIDS
Dr. Christopher Beisel, Virology Program Officer, VB, DMID
Ms. Diana Berard, Technical Assistant, EDHB, DMID
Mr. Steven Berkowitz, Acting Associate Director for Management and Operations
Dr. William Blackwelder, Chief, Biometry Branch, DMID
Ms. Nancy Blustein, Director, OPO, DAIT
Dr. James Bradac, Microbiologist, PRB, VPRP, DAIDS
Ms. Ada Brooks, Health Specialist, BSP, DAIDS
Ms. Teri Brown, Technical Information Specialist, PAB
Mr. Lawrence Butler, Contract Specialist, CMB, DEA
Ms. Sarah Carr, Director, OPA
Ms. Anne Claysmith, Health Specialist, OSC, DAIDS

Mr. Brian Collier, Administrative Officer, DAIDS
Dr. Elaine Collier, Chief, AS, CIB, DAIT
Dr. Janet Connolly, Chief, GTB, DAIT
Ms. Kristiane Cooper, Contract Specialist, CMB, DEA
Dr. George W. Counts, Director, Office of Research on Minority and Womens' Health, NIAID
Dr. George Curlin, Deputy Director, DMID
Mr. Allan Czarra, Director, Office of Program Coordination and Operations Branch, DEA
Ms. Ann Devine, Grants Management Specialist, GMB, DEA
Dr. Lawrence Deyton, Acting Director, DEA
Dr. Howard Dickler, Chief, CIB, DAIT
Dr. Carl Dieffenbach, Associate Director, BSP, DAIDS
Dr. Dennis M. Dixon, Chief, BMB, DMID
Dr. Dennis O. Dixon, Chief, CCB, TRP, DAIDS
Ms. Ann Doane, Program Assistant, OPSI, DAIDS
Ms. Laura Eisenman, Grants Management Specialist, GMB, DEA
Ms. Regina Ewig, Chief, Extramural Administrative Management Branch, NIAID
Dr. Alexandra Fairfield, Microbiologist, OIRB, TRP, DAIDS
Dr. Patricia Fast, Associate Director, VPRP, DAIDS
Ms. Irene Fishman, Statistician, PRAB, DAIDS
Dr. Mary Glenn Fowler, Deputy Branch Chief, ETB, VPRP, DAIDS
Ms. Thelma Gaither, Cytokine and Antiviral Clinical Trials Program Officer, DMID
Dr. Bruce Gellin, Medical Officer, CRAB, DMID
Dr. Ann Ginsberg, Tuberculosis, Leprosy, and Other Mycobacteria Program Officer, RDB, DMID
Ms. Janet Goldberg, Presidential Management Intern, NIAID
Dr. Robert Goldstein, Director, DAIT
Dr. Michael Gottlieb, International Tropical Diseases and Parasite Biology Program Officer, PIPB, DMID
Dr. Charles Hackett, Chief, Molecular and Structural Immunology Section, BIB, DAIT
Dr. B. Fenton Hall, Host Immunity Program Officer, PIPB, DMID
Dr. Madelon Halula, Chief, Special Review Branch, SRP, DEA
Ms. Molly Hardison, Program Analyst, OPA
Ms. Gail Havely, Program Coordinator, OSC, DAIDS
Dr. Carole Heilman, Associate Director for Scientific Program Development, DAIDS
Dr. Milton J. Hernandez, Director, OSTMD, DEA
Dr. Stephen Heyse, Medical Bacteriology and Antibacterial Resistance Program Officer, BMB, DMID
Ms. Phyllis Hill, DAIT
Dr. Penelope J. Hitchcock, Chief, STDB, DMID
Dr. Rodney Hoff, Chief, ETB, VPRP, DAIDS
Ms. Mei-wan Hoh, Technical Information Specialist, PAB
Ms. Christine Hollingsworth, FMB
Dr. Hortencia Hornbeak, Director, Scientific Review Program, DEA
Dr. Dominick Iacuzio, Influenza and Related Viral Respiratory Diseases Program Officer, RDB, DMID
Dr. Stephanie James, Chief, PIPB, DMID
Dr. Leslye Johnson, Chief, EDHB, DMID
Dr. Tina Johnson, Chief, Pediatric AIDS Clinical Trials, CSMB, TRP, DAIDS
Ms. Susan Jones, RSU, DEA
Ms. Deborah Katz, Director, OPOSI, DAIDS

Dr. John Y. Killen, Director, DAIDS
Dr. Jane Kinsel, Assistant Director for Special Projects, OD, DMID
Dr. David Klein, Bacterial Respiratory Diseases I Program Officer, RDB, DMID
Ms. Joan Kondratick, Biologist, OSC, DAIDS
Ms. Dawn Kotzen, Contract Specialist, CMB, DEA
Dr. John La Montagne, Director, DMID
Dr. Chris Lambros, Microbiology, OIRB, TRP, DAIDS
Ms. Sarah Landry, Program Analyst, OPOSI, DAIDS
Dr. Dennis Lang, Bacterial and Viral Enteric Diseases Program Officer, EDB, DMID
Dr. Catherine Laughlin, Chief, VB, DMID
Dr. Barbara Laughon, Chief, OIRB, TRP, DAIDS
Dr. Charles Litterst, Section Chief, DDCSB, TRP, DAIDS
Mr. Ron Loube, AO, DAIDS
Mr. Edward Lucas, RSU, DEA
Dr. Gary Madonna, Scientific Review Administrator, MIRB, SRP, DEA
Ms. Martha Mattheis, Chief, CRAB, DMID
Ms. Diane Martin, Program Specialist, DAIT
Ms. Margaret Matula, Health Program Officer, CSMB, TRP, DAIDS
Dr. John McGowan, Acting Deputy Director, NIAID
Mr. Paul McFarlane, Contract Specialist, CMB, DEA
Dr. Pamela McInnes, Chief, RDB, DMID
Dr. James McNamara, Chief, PMB, TRP, DAIDS
Dr. James M. Meegan, Acute Viral Infections Program Officer, VB, DMID
Dr. Nancy Miller, Microbiologist, PRB, VPRP, DAIDS
Dr. Roger Miller, Microbiologist TIB, BSP, DAIDS
Dr. Gregory Milman, Chief, PBRB, DAIDS
Dr. Paolo Miotti, Epidemiologist, EB, DAIDS
Ms. Theresa Mizell, Program Coordinator, DMID
Ms. Carolyn Mosher, Administrative Officer, EAMB
Ms. Judy Murphy, Deputy Director, OC
Ms. Jean Noe, Health Specialist, OPOSI, DAIDS
Dr. Stanley Oaks, Scientific Review Administrator, SRB, SRP, DEA
Dr. Karen Oseekey, Health Specialist, CCB, TRP, DAIDS
Ms. Diane Parris, Administrative Officer, EAMB
Ms. Cheryl Parrott, Biomedical Writer, OC
Dr. Estella Parrott, Coordinator of Research Programs, ORMWH, OD, NIAID
Ms. Mary Parsons, Health Specialist, OD, DMID
Dr. Marshall Plaut, Chief, AMS, AAIB, DAIT
Mr. William Powell, Grants Management Specialist, GMB, DEA
Dr. Olivia Preble, Chief, Microbiology and Immunology Review Branch, MIRB, DEA
Dr. Lawrence Prograis, Deputy Director, DAIT
Ms. Victoria Putrush, Grants Management Specialist, GMB, DEA
Dr. Helen Quill, Chief, BIB, DAIT
Dr. Robert Quackenbush, Assistant Director for Training, Referral and Minority Affairs, DMID
Dr. M. Sayeed Quraishi, Scientific Review Administrator, ACERRB, SRP, DEA
Dr. Regina Rabinovich, Chief, Clinical Studies Section, CRAB, DMID
Ms. Patricia Randall, Director, OC

Ms. Sahira Rafiullah, Deputy Director, OPA
Dr. Wasima Rida, Statistician, BRB, DAIDS
Mr. J. Wallace Robinson, Program Specialist, OSC, DAIDS
Dr. Stephen Rose, Chief, GTB, DAIT
Ms. Linda Rosendorf, IND Coordinator, CRAB, DMID
Dr. Daniel Rotrosen, Acting Chief, AAIB, DAIT
Ms. Joyce Sagami, Contract Specialist, CMB, DEA
Dr. Polly Sager, Chief, Office of Scientific Coordination, DAIDS
Dr. Nava Sarver, Chief, TIB, BSP, DAIDS
Dr. Leigh Sawyer, Clinical Trials Program Officer, VB, DMID
Dr. Lewis Schrager, Chief, EB, BSP, DAIDS
Dr. Alan Schultz, Chief, PRB, VPRP, DAIDS
Dr. Vicki Seyfert, Chief, Immunoregulation Section, BIB, DAIT
Ms. Mitzi Sereno, Technical Assistant, PIPB, DMID
Dr. Opendra Sharma, Health Scientist Administrator, PBRB, DAIDS
Ms. Mollie Shea, Grants Management Specialist, GMB, DEA
Mr. Vaurice Starks, Health Specialist, EB, BSP, DAIDS
Ms. Jo Ann Stesney, Program Analyst, OPCO, DEA
Dr. Allen Stoolmiller, Scientific Review Administrator, ACERRB, SRP, DEA
Dr. Paula Strickland, Scientific Review Administrator, AIDSRRC, ACERRB, SRP, DEA
Dr. Christopher Taylor, Bacterial Respiratory Diseases II Program Officer, RDB, DMID
Dr. Dianne Tingley, Chief, APRRB, SRP, DEA
Ms. LaTisha Thompkins, Program Assistant, EDHB, DMID
Ms. Carolyn Tolbert, Deputy Chief, PAB
Dr. Christopher Tseng, Antiviral Research and Antimicrobial Chemistry Program Officer, VB, DMID
Ms. Marilyn Tuttleman, Technical Assistant, BMB, DMID
Ms. Jane Unsworth, Grants Management Specialist, AIDS Division Coordinator, GMB, DEA
Ms. Brenda Velez, Chief, ACRCS. CMB, DEA
Dr. Frederick Vogel, Senior Scientist, PRB, VPRP, DAIDS
Dr. Mary Clare Walker, Microbiologist, CDB, VPRP, DAIDS
Dr. Sybil Wellstood, Microbiologist, PRAB, TRP, DAIDS
Dr. Karl Western, Assistant Director for International Research, NIAID
Mr. Thomas Williams, Acting Chief, OFM, OD, NIAID
Ms. Virginia Wilson, CMA, CMO, DEA
Ms. Melanee Woodard, Grants Financial Analyst, FMB
Ms. Joyce Woodford, Minority Health Program Coordinator, ORMWH

NIH Staff Attending:

Dr. Carlos Caban, OD/OER
Dr. Ellie Ehrenfeld, DRG
Dr. Thomas Fleisher, CC
Mr. Ronald Gress, NCI
Dr. Betty J. Hayden, DRG
Dr. Timothy Henry, DRG
Dr. Jean Hickman, DRG
Dr. Garrett Keefer, DRG
Dr. Anita Weinblatt, DRG

Dr. Eugene Zimmerman, DRG

Others:

Ms. Valerie Bartlett, HRSA/APO
Dr. Dolph Chianchiano, National Kidney Foundation
Dr. Jacquelynne Corey, AAOA
Dr. James Dickson, Harvard Medical School
Ms. Cheryl Hayden, American Academy of Dermatology
Dr. Maryanna Henkart, National Science Foundation
Mr. Nielsen Hobbs, The Blue Sheet
Dr. Larry G. Hunsicker, UNOS
Mr. Sunil Iyenyar, The Blue Sheet
Mr. Gavin Lindberg, IDF
Mr. James F. McTigue, AACTG
Ms. Tracy Mitchell, Allergy and Asthma Network/Mothers of Asthmatics
Ms. Nancy Moy, SRI International
Mr. Alfred Nugent, Midwest Research Institute
Dr. Georgia Persinos, Washington Insight
Ms. Christine Peterson, SRI International
Ms. Ann Rose Harmison, OSF
Dr. Mohamed H. Sayegh, Brigham & Women's Hospital, Harvard Medical School
Ms. Janet Shoemaker, American Society for Microbiology
Ms. Nicole Sobotka, American Lung Association
Mr. James Smith, Analytical Sciences, Inc.
Ms. Betty Wray, American College of Allergy, Asthma & Immunology

I. REVIEW OF GRANT APPLICATIONS - (Closed to the Public)

The National Advisory Allergy and Infectious Diseases Council convened in closed session on Thursday afternoon, January 23, to consider applications en bloc in the areas of allergy and immunology, microbiology and infectious diseases, and AIDS.

Pending Actions: The Council reviewed 709 research and training applications with primary assignment to NIAID for a requested amount of \$570,592,486 in first-year direct costs and recommended approval of 648 applications for \$493,376,164 in first-year direct costs. Five Method to Extend Research in Time (MERIT) awards were recommended for approval.

II. REMARKS OF THE DIRECTOR, NIAID - Anthony S. Fauci, M.D.

Dr. Fauci opened the Thursday afternoon, January 23, session of Council by welcoming visitors to the 125th meeting.

He announced the appointment of four new Council members: Dr. Robert Couch, Mr. Stephan Lawton, Ms. Emily Spitzer, and Dr. Lowell Young.

Dr. Fauci welcomed the ad hoc Council members: Dr. Abul Abbas, Professor, Department of Pathology, Harvard University; Dr. Jack Elias, Chief Pulmonary and Critical Care Medicine, Department of Internal Medicine, Yale University; Dr. Anne Gershon, Professor of Pediatrics, Department of Pediatrics, Columbia University; Dr. Susan Pierce, Professor, Department of Biochemistry, Molecular Biology and Cell Biology, Northwestern University; and Dr. Richard Whitley, Professor of Pediatrics, Microbiology and Medicine, University of Alabama (Birmingham).

A. Consideration of Minutes of Previous Meeting: The minutes of the September 26-27, 1996 meeting were considered and approved as written.

B. Dates of Future Council Meetings: May 19-20, and September 8-9, 1997; and for 1998, February 2-3, June 1-2 and September 24-25.

C. Staff and Organizational Changes:

Within the Division of AIDS (DAIDS), Dr. James McNamara has become Chief of the Pediatric Medicine Branch in the Therapeutics Research Program. Dr. Fauci announced the departure of Dr. Mary Foulkes Chief of DAID's Biostatistics and Research Branch, who left the Institute to assume a position as Associate Director for Research at SmithKline Beecham.

Ms. Sarah Carr has been appointed Director of the Office of Policy Analysis located within the Office of the Director, NIAID.

D. Review of Operating Procedures for FY 1997:

Operating procedures had been sent to Council members for review. No modifications were suggested, and they were approved.

E. Budget Update:

Congress appropriated 7.6 percent more money to the Institute in FY 1997 than it did last year, enabling NIAID to craft its FY 1997 funding policy.

- Payline at the 20.0 percentile for non-AIDS applications. 24.0 for AIDS.
- 15.0 percent average reductions to new applications.
- 3.0 percent inflationary increases to existing grants.
- Bridge awards to continue.

The Institute's success rate, is expected to increase from last year's 31.7 percent to about 32.6 percent in FY 1997.

F. Legislative Update:

Dr. Fauci informed Council of some of the changes in Congress that affect NIH. New chairpersons include Senator Jim Jeffords from Vermont, who chairs the Senate Labor and Human Resources Committee, which provides oversight and authorization to NIH, and Senator Ted Stevens, chair of the Senate Appropriations Committee.

G. Other:

Bridge Awards:

NIAID will continue its popular bridge program next year. We will be adding two new features to our bridge award program. NIAID will: 1) make awards throughout the year versus at year-end. We will implement this change in FY 1997; and 2) fund grants in a selective pay manner versus strictly by percentile. This change will take place in FY 1998, beginning with applications going to the September 1997 council round.

Malaria Meeting:

In January, a multinational malaria conference in Dakar, Senegal, drew participants from around the world. About 120 malariologists participated in the meeting sponsored by NIH, the Pasteur Institute, the Wellcome Trust, the British Medical Research Council, and others.

Attending from NIH were director Dr. Harold Varmus, DMID director Dr. John La Montagne, and staff of DMID, NIAID's Laboratory of Parasitic Diseases, and the NIH Fogarty Center.

The group split into eight focus groups to define the scientific knowledge needed to advance prevention and control and determine how to build collaborative research to obtain the necessary information.

Among the scientific initiatives that emerged are establishing collaborative research networks and enhancing Internet resources in Africa. In addition, Dr. Varmus proposed a multilateral initiative to solicit ideas for developing research networks, repositories, or collaborations. A followup meeting will likely take place in Europe in mid-summer.

AIDS Vaccine Committee (Working Group):

David Baltimore, Ph.D., Professor of Molecular Biology and Immunology at the Massachusetts Institute of Technology, is chairing a new committee to find opportunities for developing an HIV vaccine.

The Nobel Prize-winning scientist heads the AIDS Vaccine Research Committee, a working group of outside experts looking at promising scientific areas and advising NIH accordingly.

Its first meeting will be on February 17, when the group will discuss how to stimulate exploratory and developmental research in HIV vaccines.

Administratively linked to the NIAID Council, the Committee will make recommendations to NIAID, the NIH Office of AIDS Research (OAR), and other NIH components on key scientific questions.

NIAID Compliance With NIH Clinical Trials Inclusion Guidelines

A review of the data shows that clinical research applications to NIAID and NIH as a whole were 95 percent in compliance with federal guidelines for including women and minorities in clinical trials.

The 5 percent of trials that were not in compliance were initially barred from funding. These have since been revised and now comply with the regulations. NIAID will continue to work with extramural investigators to make sure their applications are in compliance with the inclusion guidelines.

Committee Reports

Dr. Glimcher reported on the Office of AIDS Research Advisory Committee meeting held in October. The Committee discussed AIDS funding, the Pediatric AIDS Clinical Trials Group, and AIDS research at the National Cancer Institute.

Dr. Warren Johnson reported on the Advisory Committee to the NIH Director meeting held in December. Major agenda items were: an update on the Clinical Center, a report on the panel looking at clinical research, a report on implementing recommendations from the Levine Panel's evaluation of AIDS research, and reviews of Institute directors.

III. ON-LINE REVIEW PILOT PROGRAM - John McGowan, Ph.D., Acting Deputy Director, NIAID

Dr. McGowan told Council how NIAID has proceeded with additional innovations for the expedited review of applications and award of grants.

Four Council rounds ago, Council began testing an Internet-based system in which members view face pages of early summary statements for investigator-initiated R01 and R29 applications within the payline. After members have completed their reviews and concurred with study section findings, NIAID can award a grant before Council. This has enabled investigators to receive their awards as much as three months earlier.

NIAID is also working with NIH's Office of Extramural Research, and the Tropical Medicine and Parasitology study section of the Division of Research Grants (DRG) to test additional innovations:

1) self-assignment of applications by investigators to study sections and institutes, 2) reduced time between the submission of applications and peer review, 3) electronically assisted peer review (reviewer critiques completed before the study section meets), 4) brief amendments (about five pages) for selected applications with minor problems for immediate reconsideration by the study section, and 5) expedited Council review.

IV. DRG UPDATE: DISCUSSION OF REINVENTION AND REVIEW ISSUES BY NEW DRG DIRECTOR - Ellie Ehrenfeld, Ph.D., Director, Division of Research Grants, NIH

Dr. Ehrenfeld introduced herself as a long-term NIAID grantee. She stated that the mission of DRG is to provide top-quality reviews. DRG has many important questions to answer to enable them to achieve their mission, and she is working together with the scientific community and NIH Institutes in this regard.

Dr. Ehrenfeld elaborated several priority areas which are receiving her attention: assessing the quality of reviews; composition of study sections, and streamlining DRG functions. Dr. Ehrenfeld responded to questions from Council.

V. EMERGING INFECTIOUS DISEASES: NIAID AND CDC ROLES -

**Stephanie James, Ph.D., Chief, Parasitology and International Programs Branch,
Division of Microbiology and Infectious Diseases, NIAID**

Dr. James began the discussion by restating the problem: new infectious diseases continue to appear (“emerge”) as a result of genetic changes, environmental pressures, and other influences, while known infectious diseases increase in incidence or change in distribution (“re-emerge”) when current control measures fail. This was illustrated by a timeline showing a number of pathogens and diseases that have appeared in the last two decades. Dr. James described the sequence of events between identification of a new infectious disease problem and its control, emphasizing the importance of both surveillance and research. She reminded the group that in a Presidential Decision Directive released in June, 1996, NIH was designated to lead Federal government efforts to strengthen research on the development of new tools to detect and control emerging infectious diseases and on the biology and pathology of infectious agents.

Dr. James described the research agenda developed by NIAID in response to this directive, which focuses on three major goals. The first goal is improved prediction and prevention of future threats, which is being addressed by support of fundamental research on the influences underlying disease emergence, as well as support of applied research on improved technology for diagnosis and prediction of outbreaks. The second major goal, development and validation of new or improved control strategies, is being addressed by applied research on drug and vaccine discovery and design, as well as evaluation through preclinical and clinical testing. The third focus of the NIAID research agenda is strengthening the national and international capacity to detect and respond to infectious disease threats, which the Institute is addressing through support of multidisciplinary research projects, focused training programs, and international research.

The implementation of these activities has taken the form of both disease-specific and approach-specific initiatives. Recent examples of the former include NIAID initiatives to expand research on Lyme and other tick-borne diseases, tuberculosis, as well as Hanta and other emerging viral infections. Recent approach-specific initiatives include drug discovery and development programs for HIV and opportunistic infections of AIDS, medically important mycoses, and emerging viral diseases. In addition, NIAID is supporting expanded research on the environmental and microbial factors influencing disease emergency, and on improved detection and prediction of emerging diseases. NIAID is also exploring the use of broader, more flexible, funding mechanisms to meet the challenge of rapid response to new infectious disease problems,

and is working closely with other groups, including the CDC, to coordinate activities. The overall intent of the NIAID research agenda is to provide an integrated, proactive, research program that will contribute to national and international preparedness to meet new infectious disease challenges.

Daniel Colley, Ph.D., Director, Division of Parasitic Diseases, National Center for Infectious Diseases, Centers for Disease Control and Prevention

Dr. Colley presented an overview to Council of some key aspects of what the Centers for Disease Control and Prevention (CDC) does, and a summary of CDC's plan for dealing with emerging and re-emerging infectious diseases, Addressing Emerging Infectious Disease Threats. He then described the current status of the implementation of this plan, which is formulated around four main goals: Surveillance and Response; Applied Research; Prevention and Control; and, Infrastructure.

To achieve enhanced surveillance and response capabilities (CDC) has begun to strengthen both U.S. and global epidemiologic and laboratory capacity. In the U.S. there are three major new competitively awarded extramural programs: 1) Emerging Infections Programs; 2) Epidemiology and Laboratory Capacity Program; and 3) several Sentinel Networks to detect emerging infections. Several intramural surveillance projects are ongoing, following internal competitions. Globally, CDC has, with NIAID, been a major participant in the Ciset deliberations and report, and its implementation. CDC has several staff detailed to the World Health Organization (WHO), specifically in regard to infectious diseases, and now supports 14 WHO Collaborating Centers at CDC, and funds over 15 intramurally-competed global emerging infections studies.

In the area of applied research, CDC has reinitiated its extramural research program by beginning in two areas: prevention and research in regard to anti-microbial resistance and tick-borne diseases. There are also competitive programs in prevention effectiveness, and in blood safety. Emerging infections-related prevention and control programs that have been implemented include: the new journal "Emerging Infectious Diseases"; funding of various conferences; support for health communications in CDC; support to the Institute of Medicine for an Emerging Infectious Disease Forum; and coordination of the multi-partner Working Group on Waterborne Cryptosporidiosis.

In response to the need to rebuild and expand the infrastructure base needed to address the threat of emerging infections, the CDC has provided the National Center for Infectious Diseases (NCID) with 75 new fulltime employees, 45 of which are supported by emerging infections funds. NCID has established a new Public Health Laboratory Training Fellowship; through a cooperative agreement with the Association of State and Territorial Public Health Laboratory directors, and now supports intramural laboratories and training infrastructural needs through a series of intramural competitions on emerging infections-related projects.

Dr. Colley then announced a proposed joint venture between NIAID and NCID to augment the epidemiologic base of research on global emerging infections. This initiative is intended to provide epidemiologic expertise and training to NIAID's ICIDR and TMRC research sites, and is being promulgated in direct response to suggestions in the Research and Training portion of the Ciset Report. This program should capitalize on the existing strengths and investments of NIAID and NCID, and thus provide added value to current programs with the focus on enhancing our global capacity to detect and deter emerging infectious disease threats.

VI. REPORT OF DIVISION OF ALLERGY, IMMUNOLOGY, AND TRANSPLANTATION COUNCIL SUBCOMMITTEE - Robert Goldstein, M.D., Director, DAIT

Drs. Charles Hackett and Vicki Seyfert have joined the Division staff as Chief of the Molecular and Structural Section and Chief of the Immunoregulation Section, Basic Immunology Branch, respectively. Dr. Hackett for the past 4 years was Director of Cellular Immunology at ImmuLogic Pharmaceutical Corp., Palo Alto, California before coming to the division. Whereas, Dr. Seyfert recently completed studies with Dr. Lou Staudt at the NCI on the role of B cell oncogenes in leukemogenesis.

Ernestine T. Smartt has been appointed the Director of the Office of Epidemiology and Clinical Trials, she has been with NIAID for more than eight years and with DAIT for five years. Ms. Smartt will be directing the second inner city asthma study, and monitoring the asthma demonstration and educational projects.

Dr. Peter J. Gergen has accepted a position, Medical Officer, at the Agency for Health Care Policy and Research, PHS. His area of interest at the agency will be child health. Dr. Gergen was with this institute for more than five years leading the inner city asthma project.

Dr. Goldstein related the following scientific activities:

NIAID/NIEHS Bi-annual Asthma Program Directors Meeting: The NIAID and the National Institute of Environmental Health Sciences (NIEHS) will hold the Bi-annual Asthma Program Directors Meeting at NIH on April 17-18, 1997. This meeting will provide a unique opportunity to present the nationwide efforts of NIAID and NIEHS to improve asthma through targeted interventions in underserved populations and through basic research.

NIH Symposium "21st Century Management of Upper Respiratory Allergic Diseases: A Focus on Allergy and Asthma": NIAID is co-sponsoring an NIH Symposium "21st Century Management of Upper Respiratory Allergic Diseases: A Focus on Allergy and Asthma" to be held in Chicago on January 13-14, 1997. This two-day symposium will focus on controversial and rapidly evolving aspects in the diagnosis and management of asthma and allergic diseases.

American College of Chest Physicians/NIAID/NHLBI Workshop on the Future of Sepsis Research: In August 1995 the American College of Chest Physicians (ACCP), NIAID, and the National Heart, Lung, and Blood Institute (NHLBI) convened a two-day workshop at NIH to discuss research needs and opportunities in the area of sepsis. An executive summary of this workshop has now been accepted for publication in Chest (February 1997).

Healthy Buildings/ IAQ '97: Global Issues and Regional Solutions: NIAID is co-sponsoring a meeting: "Healthy Buildings/ IAQ '97: Global Issues and Regional Solutions," to be held in Washington, DC, September 28-October 2, 1997. This meeting will bring together building engineers, architects and health care professionals to discuss indoor air quality as a global issue.

U.S.-Japan Cooperative Medical Sciences Program (USJCMSP): U.S.-Japan Immunology Board: The Annual Meeting of the Immunology Board of the USJCMSP was held on December 9 - 10, 1996, at the University of Hawaii in Honolulu. Scientific presentations were provided in an open session by members of both the U.S. and Japanese Boards, as well as by five ad hoc scientists invited to participate.

Results of NIAID supported African-American HLA workshop presented at annual American Society for Histocompatibility and Immunogenetics: NIAID has supported a long-term series of studies to refine the definition of HLA alleles in African Americans and to define new alleles. This 10 year effort was presented at the annual ASHI meeting this past October by Dr. Andrea Zachary of the Johns Hopkins University Immunogenetics laboratory. This study has led directly to the identification of 16 previously unknown HLA alleles in African-Americans and the refinement of the definition of the constellation of HLA haplotypes in the African-American population.

Primary Immunodeficiency Diseases Brochure: This publication provides interested parties and the general public with information about these diseases including the clinical picture, etiology, available therapy, and research opportunities.

The Genes of Primary Immunodeficiency - Windows on the Immune System and Prospects for Gene Therapy: This one-day symposium was held at the NIH on November 18, 1996. NIAID cosponsored this event with the American Academy of Allergy Asthma and Immunology, the Jeffrey Modell Foundation, and the Immune Deficiency Foundation.

Workshop on Registries for Primary Immunodeficiency Diseases: On November 19, 1996, NIAID in cooperation with the NIH Office of Rare Diseases convened a group of leading primary immunodeficiency disease investigators to review the information that had been obtained from existing registries and to consider whether registries for additional primary immunodeficiency diseases would be useful.

Workshop on Clinical Trials for Immune System Mediated Diseases: On December 6, 1996, NIAID convened a group of leading basic and clinical immunologists to consider the role that the Institute should play in clinical trials for immune system mediated diseases, including asthma and allergy, autoimmune diseases, and transplantation rejection.

ANNOUNCEMENTS AND SOLICITATIONS

IMMUNOBIOLOGICAL CONSEQUENCES OF AGING

Immunobiological Consequences of Aging, was published in the NIH Guide in October, 1996. This announcement is being co-sponsored by the NIAID, the National Institute on Aging and the National Institute of Dental Research, and is intended to stimulate research to define the scientific basis for the effects of senescence on immune function.

NIAID/AMERICAN SOCIETY OF TRANSPLANT PHYSICIANS MINORITY FELLOWSHIPS IN TRANSPLANTATION

The National Institute of Allergy and Infectious Diseases is co-sponsoring a program announcement with the American Society of Transplant Physicians. This announcement, invites applications for Individual Postdoctoral Fellowships from racial/ethnic minority individuals, women, persons with disabilities for research on the etiology, pathogenesis, diagnosis and/or treatment and prevention of transplant rejection.

CONCEPT REVIEW

Eight proposed research emphasis areas (concepts) were presented, discussed and approved.

Asthma, Allergic and Immunologic Diseases Cooperative Research Centers

The purpose of this research emphasis area is to promote and sustain innovative, multidisciplinary, and highly interactive disease-oriented basic and clinical research projects through continued support of the NIAID Asthma, Allergic and Immunologic Diseases Cooperative Research Centers (AAIDCRCs).

The Pathogenesis of Chronic Sinusitis

The purpose of this concept is to investigate the mechanisms by which viral and bacterial infections and non-infectious stimuli result in chronic inflammation and sinusitis, and to use this knowledge to develop new and more effective strategies to treat and prevent sinusitis.

Autoimmunity Centers of Excellence

The objective of this research is to support integrated centers of basic, pre-clinical and clinical research in autoimmunity. Each Autoimmunity Center of Excellence would consist of a multidisciplinary, interactive program of basic research projects focused on elucidation of the basic mechanisms of autoimmunity, understanding of self tolerance and/or immune modulation in autoimmune disease, and an integrated clinical component for piloting of new and novel immunotherapies for autoimmune disease.

Surrogate Markers of Immunologic Diseases

The research purpose is to support the development of immunologic/laboratory markers for risk assessment, diagnosis, disease activity, and/or therapeutic benefit for immunologic diseases, including asthma, allergic and autoimmune diseases, and transplantation rejection. Development of reproducible, and reliable markers for clinical therapeutic benefit are particularly sought.

Clinical Trials for Immune System Mediated Diseases

The objective of this research is to enhance the understanding of the effectiveness and mechanisms of action of immunologic interventions for human immune system mediated diseases which will lead to improved methods of treatment and prevention as well as insights into the pathogenesis of these diseases.

Cooperative Clinical Trial in Pediatric Transplantation

The goal of this research emphasis area is to continue studies to evaluate new and innovative therapeutic approaches, including evaluation of modifications in existing therapies, for enhancing graft acceptance and patient/graft survival among kidney and/or liver transplant recipients up to 18 years of age. Because of the importance of the immune system in graft acceptance/survival, this emphasis area also seeks to enhance basic knowledge about the pediatric immune system and foster the application of such knowledge in the clinical setting.

The Immune Response to Transplants of Cells and Tissues of the Nervous System

The goal of this proposed research emphasis area is to characterize the immunologic response to transplants of cells and tissues of the nervous system and to define the manner and extent to which that response affects successful engraftment. This knowledge will allow more successful use of neuro-cell transplants for a variety of neurological degenerative diseases and injuries.

Application of Data on the HLA System to the Development and Improvement of Vaccines and Influence of HLA and Other Genes on Response to Vaccines

The overall objective of this research emphasis area is to continue investigations to identify and modify the structure of peptides to increase their potency and broaden their specificity with regard to the MHC restriction elements that can recognize them and present them to the human immune system. The result of

these efforts should pave the way for testing the feasibility of peptide-based vaccines to prevent and/or treat serious human infectious diseases. Specific diseases that could be targeted with these studies include malaria, human immunodeficiency virus (HIV) infection, and hepatitis B virus (HBV) infection.

VII. REPORT OF THE JOINT MEETING OF AIDS SUBCOMMITTEE, NAAIDC, AND AIDS RESEARCH ADVISORY COMMITTEE, NIAID - John Y. Killen, M.D., Director, DAIDS

The meeting, which was held in the Natcher Conference Center on the campus of the National Institutes of Health (NIH), was chaired by Dr. Gary Nabel, chairman of the AIDS Research Advisory Committee (ARAC). Dr. Killen greeted the committee members and thanked them for their participation. He welcomed Dr. Charles Rinaldo, Jr., as a new ARAC member and mentioned that the NIAID is seeking another individual to fill a remaining ARAC position.

Dr. Killen then addressed budget issues, beginning with a brief review of the FY 1997 funding levels proposed by the President and those approved by Congress. He reported on the overall budget increases from the FY 1996 level for the NIH and NIAID, noting specific increases for NIAID's non-AIDS and AIDS research.

Addressing scientific developments, Dr. Killen described data from two recently reported studies on the transplacental carcinogenesis of AZT in mice. Data from an ongoing study being conducted by investigators at the National Cancer Institute (NCI) suggest that very high daily doses of AZT may induce tumors in the offspring of pregnant mice given the drug during the last trimester of pregnancy. A transplacental carcinogenic effect of AZT was not seen in a differently designed study carried out by scientists at Glaxo-Wellcome, Inc., (G-W) the drug's manufacturer. The G-W study attempted to model clinical usage of the drug. On January 14, 1997, NIH convened an independent panel of basic and clinical researchers, epidemiologists, HIV-infected women, and a bioethicist, to review the available data, assist the NIH in developing a scientific summary of the technically complex information, and offer recommendations for future research. The panel concluded that: the known benefits of AZT in preventing perinatal transmission far outweigh the theoretical concerns raised by the NCI mouse study; all HIV-infected pregnant women should be informed of the study results on the transplacental carcinogenesis of AZT in the course of counseling on the potential benefits and risks of treatment interventions; and all children exposed *in utero* to antiretroviral therapy, including those who are not infected with HIV, should receive careful long-term followup. The panel also outlined basic and clinical research priorities for followup on the carcinogenesis studies. Finally, the panel heard and echoed concerns that the state of the art of antiretroviral therapy has changed (e.g., the use of combination therapies) in the several years since the Public Health Service recommendations on the use of AZT to prevent perinatally acquired HIV infection were developed and suggested a reassessment of the current PHS guidelines. NIAID will broadly disseminate a summary of the available data from the NCI and G-W studies and the independent panel's recommendations to physicians, professional medical societies, and community organizations.

Dr. Killen also announced the recent appointment of Dr. David Baltimore as chair of the AIDS Vaccine Research Committee (AVRC), which has been established as a coordinating group for the overall NIH vaccine effort in response to AIDS Research Program Evaluation Working Group recommendations (Levine Report). Dr. Carole Heilman, Associate Director for Scientific Program Development for DAIDS and the NIAID point person for AVRC activities, provided an update on planned AVRC meetings and nationwide focus group discussions.

Dr. Killen then asked Dr. Marian Neutra to review the discussion and conclusions from the recent meeting organized by NIAID on mucosal immunology. Dr. Neutra reported that the participants recommended a combined empiric and basic science approach to mucosal vaccine development, with concepts tested in monkeys and humans at the same time as the underlying basic science and mechanisms are elucidated. They also recommended more coordination and direction toward encouraging and organizing the collaboration of investigators involved in mucosal transmission and mucosal vaccine research and suggested supporting more small-scale clinical studies and programs to encourage young investigators to enter the field of mucosal vaccine development.

Report on the External Review of the National Community Advisory Boards/Community Constituency Groups (NCABs/CCGs) - Mr. Martin Delaney

Dr. Killen prefaced the presentation of the report from the NCAB/CCG external review by noting that the review was conducted as part of NIAID's ongoing commitment to maintaining community involvement in clinical research within the NIAID-supported AIDS clinical research network. NIAID convened the 14-member review panel in August 1996 to evaluate the effectiveness of the NCABs/CCGs associated with the Division's clinical research and cohort studies.

Mr. Delaney, who served as a member of the panel, reviewed the findings and conclusions of the group. Overall, the review panel strongly recommended that the NCABs/CCGs continue to be assured access to and provide input on clinical research. The panel agreed that NIAID support of the NCABs/CCGs should be continued as a valuable means of bringing the AIDS constituency into the HIV/AIDS research process. The panel also offered specific suggestions regarding a variety of issues, including training programs for NCAB/CCG members, recruitment and retention of local and national CAB members, and the need for improved communication between NCAB and local CAB members. In response to one of the panel's recommendation, Ms. Rona Siskind, DAIDS, will coordinate communication across the NCABs/CCGs and will focus on broad issues that affect all of the community groups supported by the Division.

Initiative Development/Scientific Framework: Introduction - Dr. John Y. Killen

Dr. Killen introduced the presentations on the DAIDS scientific framework and proposed initiatives, noting that the goal of this meeting is to provide the joint committees with an opportunity to become involved in initiative development at an earlier stage of the NIAID priority setting process. He stated that the DAIDS scientific framework for initiative development corresponds to the research agenda outlined in the *NIAID HIV/AIDS Research Agenda*. He encouraged the committee to provide input on emerging topics for new research and identify gaps in the current and planned research portfolios.

Initiative Development/Scientific Framework: HIV Pathogenesis and Epidemiologic Research - Dr. Carl Dieffenbach

Dr. Dieffenbach provided an overview of the NIAID research program in the areas of HIV pathogenesis and epidemiology, noting that the portfolios in these areas are mainly investigator-initiated grants focused on HIV structure/function, host/pathogen interaction, HIV transmission, and disease progression. He emphasized the program priorities of encouraging novel ideas for AIDS research; expanding *in vivo* research opportunities; stimulating the movement of discoveries in pathogenesis research into vaccines, prevention, and therapeutics; and continuing the cohort studies. He also provided an overview of FY 1998 initiatives and described in broad terms those initiatives being planned for FY 1999 and beyond.

In discussion, committee members affirmed the importance of facilitating funding and evaluation of small grants for novel ideas and on translational research projects. It was noted that more trained scientists are needed in the area of animal models, particularly primate research.

Vaccine and Other Prevention Research and Development - Dr. Pat Fast

Dr. Fast described the NIAID research program in the area of vaccine and other prevention research. She stated that the operational themes of this program area are to: 1) integrate state-of-the-art research with preclinical and clinical studies using standardized evaluations and multidisciplinary collaborations, and 2) adapt to new scientific discoveries with increased administrative flexibility. The scientific themes and directions focus on HIV variation, novel vaccines, mucosal immunity, animal models, and clinical evaluation. She then summarized plans in vaccine and other prevention research for FY 1998 and beyond.

Comments from the committee addressed ensuring effective interaction of the NIAID program staff with the AIDS Vaccine Research Committee and developing mechanisms for quickly implementing recommendations that will advance the field. DAIDS staff mentioned that there are existing resources that would permit a rapid response in most circumstances. Integration of research efforts in the areas of pathogenesis, vaccines, and therapeutics, and issues pertaining to the conduct of vaccine efficacy trials were also discussed.

FY 1998 Initiatives: Concept Review/Discussion

Concept Review: Master Contract(s) for Targeted HIV Vaccine and Related Prevention Intervention Research - Dr. Alan Schultz

Under this initiative, a master contractor(s) will provide scientific management support and the flexibility to solicit qualified subcontractors in a competitive process to perform targeted research. The objective is to enable rapid mobilization of resources in response to pressing scientific needs and opportunities identified as gaps or emerging areas of importance in preclinical and clinical HIV vaccine research or other prevention intervention research. The concept was approved with one modification.

Concept Review: Laboratory Support for AIDS Vaccine and Other Prevention Clinical Trials -Dr. Mary Clare Walker

The objective of this initiative is to establish an additional central support laboratory to expand capacity for standardized high-volume humoral and cellular immunologic and virologic assays on specimens from volunteers in AIDS vaccine clinical trials and other prevention trials. This laboratory will augment the present capacity of existing laboratory contracts (the AVEG and HIVNET Central Laboratories) that support trials at domestic and international sites. The concept was approved.

Concept Review: Variation of HIV-1 and Related Lentiviruses - Dr. James Bradac

Part A: Genetic Variation of HIV-1 and Related Lentiviruses

This initiative proposes continuing funding of activities to study variation of HIV-1 and related lentiviruses to aid in the development of vaccines that are broadly reactive against all strains of the virus. The concept was approved.

Part B: Impact of HIV-1 Variation on Immunological Recognition

This initiative will fund basic research to explore the impact of variation on immune recognition and to provide information that can be utilized in the development of vaccines that are broadly reactive against many strains of HIV that are circulating in the population. The concept was approved.

Concept Review: Primate Immunology Laboratory for AIDS Vaccine Research and Development - Dr. Nancy Miller

The objectives of this initiative are to provide a centralized laboratory for assessment of the immunological responses of primates to HIV and/or SIV vaccines and to obtain comparative immunological data on a

variety of vaccines. The contract will continue to support studies conducted at NIAID's Simian Vaccine Evaluation Units (SVEUs). The concept was approved with two modifications.

Concept Review: AIDS Vaccine Evaluation Group (AVEG) Mucosal Immunology Laboratory - Dr. Mary Clare Walker

This initiative will continue support for the Mucosal Immunology Laboratory (MIL) contract that provides standardized evaluations of mucosal immune responses induced by candidate AIDS vaccines in phase I and II clinical trials conducted by the AVEG. The concept was approved with three modifications.

Initiative Development/Scientific Framework: Therapeutics Research and Development - Dr. William Duncan

Dr. Duncan provided an overview of the NIAID research program in the area of therapeutics research and development, emphasizing the need to promote linkage of basic scientists and clinicians in the therapeutics area. The therapeutics program focuses on primary disease and opportunistic infections (OIs), as well as AIDS-related neurological disease (with the National Institute of Neurological Diseases and Stroke) and malignancies (with the National Cancer Institute). He then presented the major scientific themes in the areas of primary disease, immune reconstitution/immunopathogenesis, and OIs. Dr. Duncan concluded his remarks by describing initiatives that will be implemented in FY 1998. He also discussed proposed plans in therapeutics.

In discussion, comments addressed the need to catalyze research on antiviral therapeutics in Kaposi's sarcoma, the availability of antibodies for cytokine and chemokine receptors through the AIDS Research and Reference Reagent Program, and possible strategies for conducting small-scale clinical trials.

FY 1998 Initiatives: Concept Review/Discussion

Concept Review: Preclinical Evaluation of Therapies for Treatment of Cryptococcosis - Dr. Chris Lambros

This initiative will continue support for preclinical *in vitro* testing and animal model efficacy studies of compounds with potential to treat cryptococcal meningitis associated with AIDS. The concept was approved.

Concept Review: Feline Immunodeficiency Virus (FIV) Model of AIDS - Dr. Roger Miller

This Program Announcement is focused on stimulating research on FIV molecular biology with the intent of validating the model for possible use in testing potential therapeutics, topical microbicides, and vaccines. The concept was approved.

Initiative Development/Scientific Framework: Pediatric HIV Disease - Dr. Mary Glen Fowler

Dr. Fowler described NIAID's portfolio of work directed at pediatric HIV disease, which includes research on perinatal transmission, natural history and pathogenesis, and therapeutics. The goals of this research are to reduce perinatal HIV transmission, cure acute pediatric infection, treat chronic disease in order to promote nonprogression and prolonged survival, and understand mechanisms of transmission and pathogenesis of disease progression. She also described approaches for future perinatal HIV research efforts, future directions in pediatric HIV therapeutics, and outlined initiatives proposed in FY 1999 and beyond.

The committee's discussion centered on the importance of linking basic researchers to cohort studies; how to advise women regarding the risks of transmission through breast feeding, particularly in developing

countries; difficulties in formulating drugs for children; and the status of trials of triple therapy, which has shown promise in infants but needs further study.

VIII. REPORT OF THE DMID COUNCIL SUBCOMMITTEE - John La Montagne, Ph.D. Director, DMID

Dr. John R. La Montagne, Ph.D., Director of the Division of Microbiology and Infectious Diseases (DMID), welcomed the Microbiology and Infectious Diseases Subcommittee of the National Advisory Allergy and Infectious Diseases Council and provided a brief report of Division activities. He thanked the *ad hoc* Subcommittee members Drs. Richard Whitley and Anne Gershon, and welcomed two new Subcommittee members, Dr. Robert Couch and Mr. Stephan Lawton. He also noted personnel and organizational changes since the last meeting.

Dr. La Montagne briefly discussed two DMID issues Dr. Anthony Fauci, Director, NIAID, had highlighted during the open session of Council: malaria and emerging diseases. Dr. La Montagne summarized the recent malaria research meeting in Dakar. He identified a number of initiatives that meeting participants intend to pursue, including the establishment of collaborative research networks; enhanced Internet communications in Africa; and a proposal by NIH Director Harold Varmus that the meeting's sponsors establish a "Multilateral Initiative on Malaria" to advance future efforts. A follow-up meeting is being planned for the summer of 1997.

Dr. La Montagne also acknowledged that emerging diseases continues to be a very active issue for DMID. Recently, NIAID received \$3 million from the NIH Director's reserve fund to expand emerging infectious disease research efforts. Dr. La Montagne also mentioned the U.S.-Japan Cooperative Medical Sciences Program conference held in Kyoto last July, which focused on emerging disease issues, and noted that a follow-up conference to expand discussion of these issues is planned for early March, 1997.

Dr. Ann Ginsberg provided a summary of the recent Tuberculosis (TB) Program Review. Dr. Ginsberg noted that the Institute sharply increased support for TB research during the past several years, which made it possible to fund a number of specialized TB initiatives. However, many of these initiatives will expire in the near future and therefore the Division sought the advice of outside scientific experts to help chart the course for future Institute TB research activities. Dr. Ginsberg noted the recommendations developed by the panel of experts. Dr. Couch, who chaired the panel, commented on the process as well. Dr. Ginsberg noted that the Institute had already started to respond to the recommendations, some of which are addressed by the three TB concept reviews presented (summarized below).

Dr. Dennis Lang provided a brief overview of enterohemorrhagic *E. coli* (EHEC), which has received considerable attention due to a number of recent outbreaks in both the U.S. and Japan. Dr. Lang briefly summarized a meeting that took place last November in Japan at which U.S. and Japanese scientists discussed how their cooperative efforts might address this emerging health problem.

Dr. Catherine Laughlin updated the Subcommittee on the Institute's collaborative efforts with the Department of Defense to develop drugs effective against the Ebola virus.

Three branches, the Clinical and Regulatory Affairs Branch, the Sexually Transmitted Diseases Branch, and the Virology Branch, presented information about their respective structures and research activities,

and solicited comments from the Subcommittee on their stated goals and future directions. Ms. Martha Mattheis provided an overview of the Clinical and Regulatory Affairs Branch (CRAB) and Dr. Regina Rabinovich described the research activities of the Clinical Study Section, which is a component of CRAB.

Dr. Penelope Hitchcock presented the Sexually Transmitted Diseases (STDs) Branch storyboard, providing current STD epidemiologic data and summarizing research activities managed by the Branch. Dr. Hitchcock noted that the STD Branch would undergo a programmatic review, much like the recent TB Program review, later this year. Dr. Catherine Laughlin presented an overview of the different research programs that comprise the Virology Branch.

Concept Review: Adolescents and Sexually Transmitted Diseases (STDs) Cooperative Research Center (CRC) (STDB)

The purpose of this initiative is to develop a systematic approach to assessing biological and behavioral factors that determine susceptibility to STDs during adolescence and develop effective tools and subsequently develop behavioral and biomedical interventions to control STDs in this high risk population.

Concept Review: Basic Biology, Immunology and Pathogenesis of *Mycobacterium tuberculosis* Infection (RDB)

The purpose of this Announcement is to alert the extramural research community that research in the basic biology of *M.tb* and the immunology and pathogenesis of the host-pathogen interaction is an area of need and importance to the mission of the Tuberculosis Program, Respiratory Diseases Branch, DMID, NIAID.

Concept Review: Evaluation of Vaccines in the Elderly (CRAB)

The purpose of this initiative is to advance the scientific understanding of the immunobiology of aging and to assure that older adults and the elderly receive the full benefits of immunization by evaluating existing and novel vaccines and therapeutics for infectious diseases which contribute substantial morbidity and mortality to this population.

Concept Review: Therapeutic Strategies for Papillomavirus Infections (VB)

This initiative will integrate *in vitro* and animal model evaluations of efficacy and studies of the mechanism of action of experimental therapies for papillomavirus infections. The parallel use of animal model and *in vitro* systems will facilitate studies of the mechanisms of action of any active agent.

Concept Review: Innovative Approaches to Investigating Human Tuberculosis (RDB)

The purpose of this Announcement is to alert the extramural research community that research addressed specifically to increasing our understanding of human infection by *Mycobacterium tuberculosis* is an area of need and importance to the mission of the Tuberculosis Program, Respiratory Diseases Branch, DMID, NIAID.

Concept Review: The Latent State in Tuberculosis Infection (RDB)

The purpose of this announcement is to alert the extramural research community to an area of need and importance to the mission of the Tuberculosis Program, Respiratory Diseases Branch, DMID, NIAID.

Concept Review: Repository for Biological Reagents and Reference Standards (VB)

1) To maintain and operate a suitable facility for the storage and distribution of a variety of biological reference reagents that are of importance to NIAID and to the infectious diseases research community. 2) To maintain a database system to manage an inventory and track the distribution of these reagents. 3) To

continue to accept medically important archival materials for storage, and to expand the current inventory to include new state-of-the-art products for distribution. 4) To offer scientific support services related to the existing and future inventory, including: monoclonal antibody production, quality control testing, and aliquoting of new products.

Concept Review: Research on Molecular Immunology of Sexually Transmitted Diseases (STDB)

This project will support multidisciplinary research on the molecular immunology of STDs.

Concept Review: *In Vitro* Antiviral Screens (VB)

This project will provide cell culture-based systems to evaluate compounds for their *in vitro* biological specificity in antiviral activity and cytotoxicity.

Concept Review: Research on Topical Microbicides (STDB)

The initiative will continue support for basic research, product development and clinical evaluation of topical microbicides by expansion of existing awards. The initiative focuses on critical gaps in NIAID's trans-divisional program.

IX. ADJOURNMENT

The meeting of the Council was adjourned at 4:45 p.m. on Friday, January 24, 1996.

Thursday, January 23, 1997, 8:30 a.m. - 4:00 p.m.

Friday, January 24, 1997, 8:00 a.m. - 4:45 p.m.

We do hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.

Anthony S. Fauci, M.D.
Anthony S. Fauci, M.D.
Chairman, National Advisory Allergy
and Infectious Diseases Council
Director, National Institute of Allergy
and Infectious Diseases

04/02/97
Date

Lawrence Deyton, M.D.
Lawrence Deyton, M.D.
Acting Executive Secretary
National Advisory Allergy and Infectious
Diseases Council
Acting Director, Division of Extramural Activities
National Institute of Allergy and Infectious
Diseases

03/28/97
Date

These minutes will be formally considered by the Council at its next meeting; any corrections or notations will be incorporated in the minutes at the meeting.